DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 3, 2015

Cardio-Phoenix Inc.
Marc Bisnaire, President
2102-65 Spring Garden Ave
Toronto, Ontario M2N 6H9
Canada

Re: K143432
Trade/Device Name: Cardio-TriTest
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DXR, DQC
Dated: April 22, 2015
Received: April 30, 2015

Dear Marc Bisnaire:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143432

Device Name
Cardio-TriTest

Indications for Use *(Describe)*

The intended use of this device is to acquire and record 3 different types of heart bio-signals (ECG, PCG, MCG) and combine the results into a contiguous presentation as an aid to diagnostic interpretation by a Physician in a clinical setting.

The indication for use is as…

a. a Standard 12 Lead Diagnostic ECG
b. an aid to identify events in the cardiac cycle
c. an aid to detect S1 & S2 hearts sounds and murmurs.

Not intended for use in pediatrics.
Not intended for patients in the intensive care units.
Intended population:
Males and females greater than or equal to 20 years of age.

Any diagnostic interpretation is only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

The Cardio-TriTest is on a prescription basis by a Certified Medical Practitioner.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

The assigned 510(k) number is: **K143432**

Submitter of 510(k): Cardio-Phoenix Inc.
2102-65 Spring Garden Ave
Toronto, M2N 6H9
Canada
Phone: 416-595-0795
Email: marc.bisnaire@cardiophoenix.com

Contact person: Marc Bisnaire

Date of summary: November 5th, 2014

Trade/Proprietary name: **Cardio-TriTest™**

Classification name: **EPMCG v5.5**

Classification: DPS – Electrocardiograph
DXR – Ballistocardiograph
DQC – Phonocardiograph

Product codes: DPS
DXR
DQC

The following device classifications apply to this device:

Name	Class	CFR
Electrocardiograph	II.	870.2340
Ballistocardiograph	II.	870.2320
Phonocardiograph	I.	870.2390

Classification panel: Cardiovascular

510(k) Summary

Legally marketed predicate devices:

- DIGITAL BALLISTOCARDIOGRAPH, MODEL DGB 300 (K081603)
- Zargis Acoustic Cardioscan-ZAC (K031517)

Reference device:

- 3M Littmann Electronic Stethoscope, Model 4000 (K003723)

Device Description

The Cardio-TriTest is three devices in one, combining a 12-Lead Electrocardiograph (ECG), a Phonocardiograph and a Mechanocardiograph. The device will acquire all three types of bio-signals during the same non-invasive test procedure. The three types of signals are synchronized and outputted on the same timeline making it easier and more visual for general practitioners to visually determine a patient's current heart symptoms.

The ECG component is a Standard 12-Lead ECG, conformant with IEA60601-2-25 standards.

The Cardio-TriTest device for catching ECG signals uses Standard 12-Lead FDA/CE approved ECG cables by Sino-Hero Company.

The PCG component consists of 4 electronic stethoscopes combined into one Phono recording device.

PCG/MCG sensors are with FDA/CE approved diaphragms and soft non chill rings manufactured by the Riester Company from Germany. More details:

http://www.riester.de/cardiophon.431.0.html?&L=79195

The MCG component consists of 4 MCG recording devices.

The MCG signal validation is in the Annex B of this application.

The PCG and MCG sensors are housed in common sensor housing for the purpose of being positioned/located on the thoracic wall in the same four (4) primary and standard auscultation points.

The combined PCG/MCG sensors are correctly positioned on the four primary auscultation points on the thoracic wall via a purpose designed harness.

510(k) Summary

Intended use:

The intended use of this device is to acquire and record 3 different types of heart bio-signals (ECG, PCG, MCG) and combine the results into a contiguous presentation as an aid to diagnostic interpretation by a Physician in a clinical setting.

Indication for use

The indication for use is as…

a. a Standard 12 Lead Diagnostic ECG

b. an aid to identify events in the cardiac cycle

c. an aid to detect S1 & S2 hearts sounds and murmurs.

Not intended for use in pediatrics.

Not intended for patients in the intensive care units.

Intended population:

Males and females greater than or equal to 20 years of age.

Any diagnostic interpretation is only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

The Cardio-TriTest is on a prescription basis by a Certified Medical Practitioner.

Technological characteristics and substantial equivalence:

The Cardio-TriTest (CTT) is a 3-in-1 device. It combines the functionality of an Electrocardiograph (ECG), a Phonocardiograph (PCG) and Mechanocardiograph (MCG) device into 1 device.

510(k) Summary

The value of the CTT is that it synchronizes the 3 different types of bio-signals recorded by each functional aspect of the device and visually correlates them for combined diagnostic purposes.

The technical characteristics of each functional device are either conformant to FDA approved standards in the case of the ECG functionality or substantially equivalent to their corresponding FDA approved predicate devices for the PCG and MCG functionality.

SAFETY: Being a 3-in-1 device, the safety of the device meets the Standard as per IEA60601-1, in accordance with the standards set in 60601-2-25 for Diagnostic ECG and applies equally to the two other functional aspects of the device.

In accordance with FDA guidelines, the ECG component is conformant with IEA 60601-2-25 (2014) Diagnostic ElectroCardiographs (ECG). (as such no comparison chart is produced with the other predicate devices as they do not include any ECG functionality).

The MCG functionality, acquires and records the mechanical vibrational waveforms produced by the hearts constructions and transmitted to the chest wall is substantially equivalent to the DIGITAL BALLISTOCARDIOGRAPH, MODEL DGB 300.

The PCG functionality, acquires and records the acoustic waveforms produced by the heart and is substantially equivalent to the Zargis Acoustic Cardioscan-ZAC.

The PCG signal comparison document to the Reference device is in Annex A of this application.

The MCG signal comparison document to the CTT PCG part is in Annex B of this application.

The Cardio-TriTest (CTT) device and the predicate devices listed above are indicated for use in the clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. They are not intended as a sole means of diagnosis. The interpretations of heart signals offered by CTT are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

510(k) Summary

Technological characteristics comparison table

Features and functions	DIGITAL BALLISTO CARDIOGRAPH, MODEL DGB 300	Zargis Acoustic Cardioscan (ZAC)	Cardio-TriTest v5.5
Device Type	**BCG[1]**	**PCG**	**ECG/PCG/ MCG(BCG)**
Software			
Test stored as individual files	YES	YES	YES
Save tests	YES	YES	YES
File retrieval	From Hard Drive or external drive	From Hard drive	From Hard drive
Operating system	Windows XP, Windows Vista	Windows XP SP2 or later or Vista 32-bit	Windows 7, Windows 8.x (32 or 64bit)
PC-based software	YES	YES	YES
Printing	YES	YES	YES
Networked	NO	N/A	NO
Modem data transfer	NO	N/A	NO
Display sounds in time and frequency domain	N/A	YES	YES - in time domain
Recording test			
Saving signals just of acceptable quality	N/A	YES	YES
Reporting errors during recording	N/A	YES – voice prompt	YES – written prompt
Indication of the failure cause and suggested corrective action	N/A	YES	YES
Re-recording ability	N/A	YES	YES
ECG -BCG Synchronized Stacked Display	Yes (ECG & 3 Axis BCG)	N/A	Yes (ECG & PCG & MCG(BCG))

[1] References to BCG and MCG refer to the same accelerometer generated signal but a different naming convention is used, Other names include Vibrocardiograph (VCG), Seismocardiograh (SCG) and all are substantially equivalent to MCG. The literature is confusing as they are often used interchangeably.

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Rhythm Strip	YES	N/A	YES
ECG	No, Single Lead Rhythm Strip	N/A	YES, 12-lead ECG
X axis BCG	YES	N/A	YES
Y axis BCG	YES	N/A	YES
Z axis BCG	YES	N/A	YES
XYZ combined	NO	N/A	YES
Preset recording time	User configurable 10, 30, 60 sec	User configurable 1 – 20 sec	User configurable 30, 60, 120, 180, 300 seconds
Pre exercise test	YES	N/A	YES
Post exercise test	YES	N/A	N/A
Data recording	N/A	standard .wav and Native .zac file	24bit binary and zipped
Acoustic sensor	N/A	Electronic stethoscope	Electronic stethoscope
Number of sensors	N/A	1	4
Waveform review			
Waveform markers	Yes, User Applies Markers for ACC recognized waves (Mitral Valve Close, J, Mitral Valve Open, Aortic Value Open, Aortic Valve Close, Early Diastole)	N/A	NO Not required for Intended Use
Scroll BCG	YES	N/A	YES
Zoom BCG	YES	N/A	YES
Measurement	YES	N/A	YES
Signal averaging	YES	N/A	NO
Zoom option	YES	YES	YES
Scroll option	YES	YES	YES
Digital filtering	N/A	YES – 3 modes: Bell mode, Diagraph mode and Extended mode	YES 4 kind of ECG filter, 1 PCG, 1 BCG/MCG
Heart sound analysis	YES	YES	NO
Lung sound analysis	NO	NO	NO
Number of display panels	N/A	4	3

Identifying presented specific heart sounds	N/A	S1, S2	S1, S2
Graphically displays heart wave intensity, timing and location	N/A	YES	NO
Spectrogram view	N/A	YES	NO
Wavelet view	N/A	YES	NO
Hardware			
Portable unit	Portable hand held unit	N/A	Transportable unit
Battery power	YES	N/A	NO
Tri-axial accelerometer	YES	N/A	YES
ECG Lead Wires	No (ECG adhesive patches applied to sensor and patient)	N/A	YES
Data transmitting	Wireless Bluetooth transmission from dBG 300 device to dBG Software on a PC	N/A	USB 2.0
PC connection – input type	N/A	USB wireless dongle	USB port
Display requirement	N/A	1024 x 600 graphic display or better	1024 x 600 graphic display or better
Connectivity	N/A	USB 1.1 port or better	USB 2.0 +
Bluetooth	N/A	YES	N/A

Any differences in technical characteristics, such as differences in Windows OS systems, type and number of sensors, preset recording time, data transmission type, power supply type, recording format, number of display panels, PC connection type do not raise any significant concern with respect to the safety or on the effectiveness of the operating results.

Safety and performance

The Cardio-TriTest is a 3-in-1 device. The criteria for safety is governed best by the ECG functionality which is subject to FDA approved safety standard set out in

510(k) Summary

IEA60601-1. The Cardio-TriTest device has passed all the required safety standards and has also been subjected to extensive safety, environmental and performance testing.

Final testing for the device included various performance tests, including software validation corresponding to each functional aspect of the device, to ensure that all safety and performance specifications were met.

The Cardio-TriTest device has also been tested to assure compliance to the requirement of various published standards including the following:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-25
- IEC 60601-1-6
- EC53
- ISO 13485
- ISO 14971

Conclusion:

Based upon the each predicates corresponding indications for use, their technological characteristics and their safety and performance testing, the Cardio-TriTest has been shown to be substantially equivalent to the corresponding above listed legally marketed predicate devices under the Federal Food, Drug, and Cosmetic Act.